

Message Text

UNCLASSIFIED

PAGE 01 STATE 005215
ORIGIN HEW-06

INFO OCT-01 ARA-10 ISO-00 OES-06 /023 R

DRAFTED BY DHEW/FDA: JRWEINROTH, M.D.:CCK
APPROVED BY OES/APT/BMP: WJWALSH, III
DHEW/OIH: BROYSTER
ARA/AND:RSPACE(INFO)

-----110222Z 129923 /63

R 102243Z JAN 77
FM SECSTATE WASHDC
TO AMEMBASSY LA PAZ

UNCLAS STATE 005215

E.O. 11652: N/A

TAGS: OGEN, ETRD, TBIO, BL,

SUBJECT: ERRATIC FILLED DRUG VIALS (RECALL NO. D-056-7)

1. FDA ADVISES OF THE FOLLOWING DRUG RECALL:

PRODUCT INVOLVED: AMPHOTERICIN B, USP, 50MG. VIAL, LYOPHILIZED POWDER, FOR PARENTERAL ADMINISTRATION. THE PRODUCT IS SOLD ON A PRESCRIPTION BASIS AND IS USED AS A FUNGISTATIC.

PRODUCT IDENTIFICATION: FUNGIZONE INTRAVENOUS LOT NOS. 6B644, EXPIRATION DATE 2/78.

MANUFACTURING FIRM:

E. R. SQUIBB AND SONS, INC.
GEORGES ROAD
NEW BRUNSWICK, NEW JERSEY 08903

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RECALLING FIRM: E.R. SQUIBB AND SONS INC., PRINCETON, N.J.

REASON FOR RECALL: THE FIRM NOTIFIED FDA REGARDING A COMPLAINT RECEIVED ON UNDER-FILLED VIALS. A FOLLOW-UP INVESTIGATION REVEALED INSTANCES OF BOTH UNDER AND OVER
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FILLING IN THIS LOT. THIS RECALL HAS BEEN CLASSIFIED AS CLASS III - A SITUATION IN WHICH THE USE OF, OR EXPOSURE TO A VIOLATIVE PRODUCT IS NOT LIKELY TO CAUSE ADVERSE HEALTH CONSEQUENCES.

2. POST IS REQUESTED TO INFORM FOREIGN CONSIGNEE WHO IS LISTED AS WILLIAM STEDMAN, U.S. AMBASSADOR, LA PAZ, BOLIVIA, WHO APPARENTLY AUTHORIZED ORDER FOR THREE HUNDRED VIALS WHICH WERE RECEIVED ON 10 JUNE 1976. THE FIRM MAILED LETTERS TO ALL ACCOUNTS DATED 15 NOVEMBER 1976 CONCERNING THIS RECALL. ANY QUESTIONS REGARDING THE RECALL SHOULD BE DIRECTED TO R.COWLES AT SQUIBB AND SONS INC., PRINCETON, N.J., TELEPHONE 201-545-5878.
KISSINGER

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NNN

Message Attributes

Automatic Decaptioning: X
Capture Date: 01-Jan-1994 12:00:00 am
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: DRUGS, RECALLS
Control Number: n/a
Copy: SINGLE
Sent Date: 10-Jan-1977 12:00:00 am
Decaption Date: 01-Jan-1960 12:00:00 am
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01-Jan-1960 12:00:00 am
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1977STATE005215
Document Source: CORE
Document Unique ID: 00
Drafter: JRWEINROTH, M.D.:CCK
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Expiration:
Film Number: D770009-0899
Format: TEL
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1977/newtext/t19770165/aaaacfel.tel
Line Count: 77
Litigation Code IDs:
Litigation Codes:
Litigation History:
Locator: TEXT ON-LINE, ON MICROFILM
Message ID: 17e9b6db-c288-dd11-92da-001cc4696bcc
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 2
Previous Channel Indicators: n/a
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: n/a
Retention: 0
Review Action: RELEASED, APPROVED
Review Content Flags:
Review Date: 15-Oct-2004 12:00:00 am
Review Event:
Review Exemptions: n/a
Review Media Identifier:
Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
SAS ID: 3630484
Secure: OPEN
Status: NATIVE
Subject: ERRATIC FILLED DRUG VIALS (RECALL NO. D-056-7)
TAGS: OGEN, ETRD, TBIO, BL
To: LA PAZ
Type: TE
vdkgvwkey: odb://SAS/SAS.dbo.SAS_Docs/17e9b6db-c288-dd11-92da-001cc4696bcc
Review Markings:
Margaret P. Grafeld
Declassified/Released
US Department of State
EO Systematic Review
22 May 2009
Markings: Margaret P. Grafeld Declassified/Released US Department of State EO Systematic Review 22 May 2009